Re-evaluation Decision RVD2010-07

Tefluthrin

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Re-evaluation Decision for Tefluthrin

After a re-evaluation of the insecticide tefluthrin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act,* is granting continued registration of tefluthrin products for sale and use in Canada.

An evaluation of available scientific information found that, under the revised conditions of use, tefluthrin products have value in the food and crop industry and do not present unacceptable risks to human health or the environment. As a condition of the continued registration of tefluthrin for use on field corn, sweet corn and seed corn, new risk reduction measures are required. Additional data are being requested.

The regulatory approach regarding the re-evaluation of tefluthrin was first proposed in the consultation document,[1] Proposed Re-evaluation Decision PRVD2010-01, *Tefluthrin*. This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process concerning the re-evaluation of tefluthrin and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-01, *Tefluthrin*. To comply with this decision, registrants of products containing tefluthrin will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in PRVD2010-01, *Tefluthrin*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive segments of the population in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides.

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Health Canada's website at healthcanada.gc.ca/pmra.

What is Tefluthrin?

Tefluthrin is a synthetic pyrethroid insecticide (Resistance Management Mode of Action (MoA) Group 3), registered to control northern corn rootworm, western corn rootworm, black cutworm, wireworm and seedcorn maggot in field corn, sweet corn and seed corn. It is applied to the soil at planting using conventional ground equipment by farmers, farm workers and professional applicators.

Health Considerations

Can Approved Uses of Tefluthrin Affect Human Health?

Additional risk-reduction measures are required on tefluthrin labels. Tefluthrin is unlikely to affect your health when used according to the revised label directions.

Potential exposure to tefluthrin may occur through the diet (food and water), applying the product or, to a lesser extent, by entering treated sites. When assessing health risks, two key factors are considered: the dose levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when tefluthrin products are used according to label directions.

Tefluthrin showed high acute toxicity to mice by the oral route of exposure and to rats by the oral, inhalation and dermal routes of exposure. In rabbits, tefluthrin was slightly to minimally irritating to the skin and was severely irritating to the eye. Tefluthrin was not a potential skin sensitizer in guinea pigs.

There was no evidence that tefluthrin was genotoxic or teratogenic. In female rats, there was evidence of carcinogenicity in the form of uterine adenocarcinomas. Benign liver tumours were observed in female mice. Tefluthrin did not cause cancer in male mice or rats. The major target organ for tefluthrin in repeat-dose toxicological testing was the nervous system with signs typical of pyrethroid toxicity reported in all species examined by the oral route and in rats examined by the dermal route. Tefluthrin's effect on organ weights and histopathology suggest that the liver is also a target organ in all examined species.

When tefluthrin was given to pregnant animals, an enhancement of clinical signs of neurotoxicity was noted with multigenerational exposure. Based on evidence of neurotoxicity in the offspring in the absence of parental toxicity, there is a sensitivity of the young animal to tefluthrin. Additional studies are required.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Occupational Risks from Handling Tefluthrin

Occupational risks are not of concern when used according to the revised label directions.

Occupational risks (mixing, loading and applying product) are not of concern for agricultural scenarios, provided additional protective measures are followed. Based on the precautions and directions for use on the registered product labels, non-cancer risk estimates associated with certain mixing, loading and applying activities did not meet current standards and are of concern. However, the uses for agricultural scenarios will meet the targets when engineering controls and personal protective equipment are used. These measures are needed to minimize potential exposure and protect worker's health.

Cancer risks are not of concern.

Postapplication risks are not of concern when used according to the revised label directions.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. No data exists to adequately assess postapplication exposure to tefluthrin from areas treated with a granular product that has been incorporated into the topsoil. However, due largely to the relatively low application rate and the nature of the application, no significant exposure risk is expected to occur following a tefluthrin treatment. The only potential source of exposure would result from agricultural workers walking or working on recently treated soil at planting. A restricted-entry interval set at 12 hours will mitigate any risk (both non-cancer and cancer) of exposure for postapplication workers entering an area that has been treated with tefluthrin granules.

Cancer risks are not of concern.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no residential uses of tefluthrin. Given that homeowners would not be applying the product, a risk assessment for this scenario was not conducted.

Residues in Water and Food

Dietary risks from food and water are not of concern when used according to the revised label directions.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to tefluthrin from residues in treated crops and drinking water, including the most sensitive subpopulation (children one to two years old), was estimated. This aggregate exposure (to tefluthrin from food and drinking water) was less than 76% of the acute reference dose (ARfD) and 9.4% of the chronic reference dose.

The lifetime cancer risk was 0.4×10^{-6} and is considered acceptable. A lifetime cancer risk that is less than 1×10^{-6} does not indicate an unacceptable risk for the general population when exposure occurs through pesticide residues in or on food, and to otherwise unintentionally exposed persons. Further information on how the potential cancer risks from pesticides are assessed can be found in Science Policy Notice SPN2000-01, *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*.

Based on metabolism data, the residue definition in all commodities is the parent compound, tefluthrin (2,3,5,6-tetrafluoro-4-methylbenzyl (Z)-(1RS)-cis-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate) and its metabolite (cis-3-(2-chloro-3,3,3,trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate). With this residue definition, a maximum residue limit (MRL) of 0.001 ppm was established for milk. An MRL of 0.06 ppm was proposed for field corn and sweet corn kernels plus cob with husks removed, in the Proposed Re-evaluation Decision PRVD2010-01, *Tefluthrin*.

Environmental Considerations

What Happens When Tefluthrin is Introduced Into the Environment?

Tefluthrin poses a potential risk to certain terrestrial and aquatic organisms. Therefore, additional risk-reduction measures need to be observed.

Tefluthrin is an intermediate to high volatility substance. However, it is applied as a granular with subsurface placement and volatilization is substantially impeded. In addition, tefluthrin phototransforms rapidly in air and its half life is less than a day. However, tefluthrin is a granular product, which is buried during application and so volatilization of tefluthrin to the air is reduced. It is a moderately persistent substance in the soil and water and it is persistent in sediment. Biotransformation is the dominant mode of transformation in the soil and aquatic systems. Tefluthrin is an insoluble and highly adsorptive material that readily bonds to soil and sediment. It does not leach to groundwater. Its presence in runoff occurs when soil mineral matter containing adsorbed tefluthrin becomes mobile. The log octanol-water partition coefficient is high, which indicates a potential for bioaccumulation. However, tefluthrin does not meet all the criteria under the Toxic Substances Management Policy to be considered as a Track 1 substance.

Tefluthrin was not found to be a risk to earthworms. Bees and beneficial insects are not expected to be exposed to tefluthrin, which is applied as a granular product. Mammals were found to be at risk from inadvertent consumption of tefluthrin granules while foraging for food. Soil mineral matter can be attached to invertebrates and plant material that mammals consume as food sources. Small birds were found to be at risk from consumption of tefluthrin granules as grit. Large non-granivorous birds were found to be at significant risk from inadvertent consumption of granules with food sources. Although tefluthrin is applied as an in-furrow or banded granular application, both field studies and modelling show that runoff events can yield enough tefluthrin to present acute and chronic risks to freshwater fish and amphibians and a risk to freshwater and estuarine/marine invertebrates and estuarine/marine fish. Tefluthrin is not a risk to algae or aquatic plants.

Although tefluthrin presents some risks to small mammals and birds and some aquatic organisms, these risks can be reduced with advisory label statements.

Value Considerations

What is the Value of Tefluthrin?

Tefluthrin is needed for rotation with neonicotinoids for the purpose of resistance management.

For the purpose of resistance management, tefluthrin (a resistance MoA Group 3 insecticide) is needed for rotation with products formulated with active ingredients from a different resistance MoA group.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of tefluthrin, the PMRA is requiring further risk-reduction measures for product labels.

Additional Key Risk-Reduction Measures:

- **Human Health**
    - To protect mixer/loader/applicators: additional protective equipment and restricted-entry intervals are required.
    - To minimize residues: replant intervals and preharvest intervals are required.
- **Environment**
    - To reduce the release of tefluthrin into the environment for the protection of terrestrial and aquatic habitats that may contain sensitive species: additional advisory statements to reduce runoff and to protect non-target species are required.

What Additional Scientific Information is Being Requested?

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrants of the technical active ingredients by the PMRA.

Chemistry

DACO 2.13.4 Impurities of human health or environmental concern

Human Health

DACO 4.5.12 Acute neurotoxicity study
DACO 4.5.13 90-day neurotoxicity study
DACO 4.5.14 Developmental neurotoxicity study
DACO 6.2 Poultry metabolism study to confirm goat metabolism
DACO 7.2.2 Validated enforcement methods for all components of the tefluthrin residue definition in animal tissue, milk and eggs

The following data may be required for continued registration depending on the results of the submitted poultry metabolism data for DACO 6.2:

DACO 7.5 Poultry and egg residue data from feeding of treated crops

Other Information

The risk assessments found in the PRVD2010-01, *Tefluthrin*, serves as an evaluation report. The relevant test data on which the re-evaluation decision is based on are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa, ON, Canada). For more information, please contact the PMRA's Pest Management Information Service.
Any person may file a notice of objection[5] regarding this decision on tefluthrin within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.